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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,997	02/02/2004	Claus Riehle	PO-8010/LeA 36,342	2148

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EXAMINER

SUNG, CHRISTINE

ART UNIT PAPER NUMBER

2884

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/769,997

Applicant(s)

RIEHLE ET AL.

Examiner

Christine Sung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Amendment

1. The amendment filed on March 3, 2006 has been accepted and entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hallinan (US Patent 6,103,934 A) in view of NPL David Firth Reference "Nitration Reactions in the manufacture of Pharmaceutical Intermediates."

Regarding claim 1, Hallinan discloses a process for monitoring and controlling process for monitoring and/or controlling at least one process comprising:

- a) measuring spectrometrically (claim 2) an online composition of an acid phase reaction mixture (claim 1),

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b) relaying data from a) to a process control system in order to monitor and to control the production process (claim 1).

Hallinan does not specify that the process for monitoring and controlling is for a nitration reaction. However nitration reactions are used in making many products such as pharmaceutical products and such a process is well known (see attached Firth NPL Reference "Nitration Reactions in the manufacture of Pharmaceutical Intermediates."). One of ordinary skill in the art would be motivated to adapt the process as disclosed by Hallinan with the nitration process as disclosed by Firth in order to efficiently mass produce pharmaceutical products by reducing the processing time.

Regarding claim 2 and 3, Hallinan discloses using an infrared spectrometer (claim 2).

Regarding claim 4, Hallinan discloses using a measuring cell (figure 1, box where IR analyzer is located) is located in a by pass.

Regarding claim 5, Hallinan discloses that the data are based on the spectrometric online measurement and evaluation with a matrix-specific calibration model (column 10, lines 49-53).

Regarding claim 6, Hallinan discloses that the spectrum obtained by online measurement is evaluated with a matrix-specific calibration model based on comparative titration measurements (column 111, lines 56-61).

Regarding claim 7, Hallinan does not specify the exact materials being monitored, however, as stated above, the nitration process, and the subsequent materials used in the reaction process, is known for pharmaceutical manufacture.

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Regarding claims 8-9, Hallinan discloses the a means for performing spectrometric measurements with an evaluating unit (see above and claim 1), but does not explicitly state measuring at multiple points of the reaction process. However, one of ordinary skill in the art would be motivated to use multiple measuring points in order to accurately gauge the reaction process, thus increasing the accuracy in monitoring and controlling production of the desired product, and reducing excess or waste of materials.

Regarding claim 10, Hallinan discloses a product capable of automatically implementing the steps of:

a) evaluating data obtained by a spectrometric examination of an acid phase after reaction to determine the content of acid in the acid phase (claim 1 and 2, using spectrometer to measure acid phase), and

b) relaying the nitric-acid content data from a) to a regulator to control metering of acid to a reaction mixture (claim 1).

Hallinan does not specify that the process for monitoring and controlling is for a nitration reaction. However nitration reactions are used in making many products such as pharmaceutical products and such a process is well known (see attached Firth NPL Reference "Nitration Reactions in the manufacture of Pharmaceutical Intermediates."). One of ordinary skill in the art would be motivated to adapt the process as disclosed by Hallinan with the nitration process as disclosed by Firth in order to efficiently mass produce pharmaceutical products by reducing the processing time.

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Regarding claim 11, Hallinan discloses that the data are based on the spectrometric online measurement and evaluation with a matrix-specific calibration model (column 10, lines 49-53).

Regarding claim 12, Hallinan discloses that it is designed for automated regulation of the reaction process (claim 1).

Regarding claim 13, Hallinan discloses a facility for monitoring and/or controlling a reaction process comprising:

a) means for spectrometric examination of an acid phase after a nitration (claim 1), and

b) regulating means for metering nitric acid into at least one nitrating reactor, the regulating means being designed to regulate metering of acid on the basis of the spectrometric examination. (claim 1 and 2).

Hallinan does not specify that the process for monitoring and controlling is for a nitration reaction. However nitration reactions are used in making many products such as pharmaceutical products and such a process is well known (see attached Firth NPL Reference "Nitration Reactions in the manufacture of Pharmaceutical Intermediates."). One of ordinary skill in the art would be motivated to adapt the process as disclosed by Hallinan with the nitration process as disclosed by Firth in order to efficiently mass produce pharmaceutical products by reducing the processing time.

Regarding claim 14 and 15, Hallinan discloses using an infrared spectrometer (claim 2).

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Regarding claim 16, Hallinan discloses using a measuring cell (figure 1, box where IR analyzer is located) is located in a by pass.

Regarding claims 17 and 20, Hallinan discloses that the spectrum obtained by online measurement is evaluated with a matrix-specific calibration model based on comparative titration measurements (column 111, lines 56-61).

Regarding claims 18 and 21-22, Hallinan discloses the a means for performing spectrometric measurements with an evaluating unit (see above and claim1), but does not explicitly state measuring at multiple points of the reaction process. However, one of ordinary skill in the art would be motivated to use multiple measuring points in order to accurately gauge the reaction process, thus increasing the accuracy in monitoring and controlling production of the desired product, and reducing excess or waste of materials.

Regarding 19 and 23-24, Hallinan discloses having a process control system (figure 1) for the regulating means and a connection of the means for spectrometric examination (IR ANALYZER) to the process control system (Figure 1).

Response to Arguments

5. Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Sung whose telephone number is 571-272-2448. The examiner can normally be reached on Monday- Friday 7-3 pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christine Sung
Examiner
Art Unit 2884

CS



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